IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

PFIZER INC., PHARMACIA CORP., PHARMACIA & UPJOHN INC., PHARMACIA & UPJOHN COMPANY, G.D. SEARLE & CO., G.D. SEARLE LLC, SEARLE LLC (DELAWARE) and SEARLE LLC (NEVADA) Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	CIVIL ACTION No: **COMPLAINT**

Pfizer Inc., Pharmacia Corp., Pharmacia & Upjohn Inc., Pharmacia & Upjohn Company, G.D. Searle & Co., G.D. Searle LLC, Searle LLC (Delaware), and Searle LLC (Nevada) (collectively, "Pfizer"), by its attorneys, for its complaint against Teva Pharmaceuticals USA, Inc. ("Teva") alleges as follows:

1. This is an action by Pfizer against Teva for infringement of United States Patent Nos. 5,466,823 ("the '823 patent"), 5,563,165 ("the '165 patent") and 5,760,068 ("the '068 patent").

JURISDICTION AND VENUE

2. This action arises under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331 and 1338.

3. Upon information and belief, Teva is subject to personal jurisdiction in this district.

4. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

THE PARTIES

5. Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 235 East 42nd Street, New York, New York. Pfizer Inc. invests extensively in designing, developing, testing and evaluating new and innovative pharmaceutical products and it sells pharmaceutical products to the public throughout the United States.

6. Pharmacia Corp. is a corporation organized under the laws of the State of Delaware and is a wholly-owned subsidiary of Pfizer Inc.

7. Pharmacia & Upjohn Inc. is a corporation organized under the laws of the State of Delaware and is a wholly-owned subsidiary of Pharmacia Corp.

8. Pharmacia & Upjohn Company is a corporation organized under the laws of the State of Delaware and is a wholly-owned subsidiary of Pharmacia Upjohn, Inc.

9. G.D. Searle & Co. was a corporation organized under the laws of the State of Delaware with a place of business at 7000 Portage Road, Kalamazoo, Michigan. On December 31, 2000, G.D. Searle & Co. was converted to G.D. Searle LLC, a limited liability company

under the laws of the State of Delaware. G.D. Searle LLC is a wholly owned subsidiary of Pharmacia & Upjohn Company.

10. Searle LLC (Delaware) is a limited liability company organized under the laws of the State of Delaware and is a wholly-owned subsidiary of G.D. Searle LLC.

11. Searle LLC (Nevada) is a limited liability company organized under the laws of the State of Nevada and is a wholly-owned subsidiary of G.D. Searle LLC.

12. Upon information and belief, Teva is a corporation organized and existing under the laws of the State of Delaware and has places of business in Fairfield, New Jersey and Elmwood Park, New Jersey.

13. Upon information and belief, Teva is in the business of making and selling generic pharmaceutical products which it distributes in the State of New Jersey and throughout the United States.

14. Upon information and belief, Teva assembled and caused to be filed with the United States Food and Drug Administration (the "FDA"), pursuant to 21 U.S.C. § 355(j)(2), Abbreviated New Drug Application No. 76-898 ("ANDA No. 76-898"), addressed to a proposed drug product identified as "Celecoxib Capsules, 100 mg, 200 mg, and 400 mg" ("Teva Celecoxib Capsules").

FIRST CLAIM FOR RELIEF: INFRINGEMENT OF THE '823 PATENT

15. Pfizer realleges paragraphs 1 through 14 above as if fully set forth herein.

16. On November 14, 1995, the United States Patent and Trademark Office ("the PTO") issued the '823 patent, entitled "Substituted Pyrazolyl Benzenesulfonamides," based on an application filed by John J. Talley, *et al.*, which had been duly and legally assigned to G.D. Searle & Co. Pfizer currently holds title to the '823 patent. A copy of the '823 patent is attached hereto as Exhibit A.

17. The '823 patent discloses and claims, inter alia, a class of pyrazolyl benzenesulfonamide compounds for use in treating inflammation and inflammation-associated disorders.

18. Pfizer holds an approved New Drug Application for celecoxib capsules, 100 mg, 200 mg and 400 mg dosage strengths, which it sells under the registered name Celebrex®. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA promulgated pursuant thereto, the '823 patent is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to the Celebrex® drug product. Celebrex® is approved for the treatment of various inflammation-associated disorders.

19. The Orange Book lists the '823 patent's expiration date as November 30, 2013.

20. Pfizer received from Teva a "Notice of Paragraph IV Certification," dated January 6, 2004, stating that Teva had filed ANDA No. 76-898 with the FDA, seeking approval to market and sell its Teva Celecoxib Capsules before the '823 patent's expiration date of November 30, 2013, as listed in the Orange Book ("Teva's Notice Letter").

21. Teva's Notice Letter states that Teva's ANDA No. 76-898 certifies, pursuant to 21 U.S.C. § 355(j)(2)(B)(i) and (ii) ("Paragraph IV certification[] with respect to ... the '823 patent"), that the '823 patent is invalid, unenforceable and/or would not be infringed by Teva's manufacture, use or sale of its Teva Celecoxib Capsules.

22. Teva has infringed the '823 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA ANDA No. 76-898, which includes the paragraph IV certification as to the '823 patent and which seeks approval from the FDA to engage in the commercial

manufacture, use, or sale of its Teva Celecoxib Capsules prior to the expiration of the '823 patent.

23. Upon information and belief, Teva is committed to selling and intends to commercially sell its Teva Celecoxib Capsules promptly following FDA approval of ANDA No. 76-898.

24. Upon information and belief, Teva has knowingly and willfully infringed the '823 patent.

25. Pfizer will be irreparably harmed if Teva is not enjoined from infringing the '823 patent.

SECOND CLAIM FOR RELIEF: INFRINGEMENT OF THE '165 PATENT

26. Pfizer realleges paragraphs 1 through 25 above as if fully set forth herein.

27. On October 8, 1996, the PTO issued the '165 patent, entitled "Substituted Pyrazolyl Benzenesulfonamides for the Treatment of Inflammation," based on an application filed by John J. Talley, *et al.*, which had been duly and legally assigned to G.D. Searle & Co. Pfizer currently holds title to the '165 patent. A copy of the '165 patent is attached hereto as Exhibit B.

28. The '165 patent discloses and claims, inter alia, pharmaceutical compositions comprising a compound selected from a class of pyrazolyl benzenesulfonamide compounds for use in treating inflammation and inflammation-associated disorders.

29. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA promulgated pursuant thereto, the '165 patent is listed in the Orange Book with respect to the Celebrex® drug product.

30. The Orange Book lists the '165 patent's expiration date as November 30, 2013.

31. Teva's Notice Letter also states that Teva's ANDA No. 76-898, filed with the FDA, seeks approval to market and sell its Teva Celecoxib Capsules before the '165 patent's expiration date of November 30, 2013, as listed in the Orange Book.

32. Teva's Notice Letter states that Teva's ANDA No. 76-898 certifies, pursuant to 21 U.S.C. § 355(j)(2)(B)(i) and (ii)("paragraph IV certification[] with respect to ... the '165 patent"), that the '165 patent is invalid and/or would not be infringed by the manufacture, use or sale of its Teva Celecoxib Capsules.

33. Teva has infringed the '165 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA ANDA No. 76-898, which includes the paragraph IV certification as to the '165 patent and which seeks approval from the FDA to engage in the commercial manufacture, use, or sale of its Teva Celecoxib Capsules prior to the expiration of the '165 patent.

34. Upon information and belief, Teva is committed to selling and intends to commercially sell its Teva Celecoxib Capsules promptly following FDA approval of ANDA No. 76-898.

35. Upon information and belief, Teva has knowingly and willfully infringed the '165 patent.

36. Pfizer will be irreparably harmed if Teva is not enjoined from infringing the '165 patent.

THIRD CLAIM FOR RELIEF: INFRINGEMENT OF THE '068 PATENT

37. Pfizer realleges paragraphs 1 through 36 above as if fully set forth herein.

38. On June 2, 1998, the PTO issued the '068 patent, entitled "Substituted Pyrazolyl Benzenesulfonamides for the Treatment of Inflammation," based on an application filed by John J. Talley, *et al.*, which had been duly and legally assigned to G.D. Searle & Co.

Pfizer currently holds title to the '068 patent. A copy of the '068 patent is attached hereto as Exhibit C.

39. The '068 patent discloses and claims, inter alia, methods of treating inflammation and inflammation-associated disorders comprising administering a compound from a class of pyrazolyl benzenesulfonamide compounds.

40. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA promulgated pursuant thereto, the '068 patent is listed in the Orange Book with respect to the Celebrex® drug product.

41. The Orange Book lists the '068 patent's expiration date as June 2, 2015.

42. Teva's Notice Letter also states that Teva's ANDA No. 76-898, filed with the FDA, seeks approval to market and sell its Teva Celecoxib Capsules before the '068 patent's expiration date of June 2, 2015, as listed in the Orange Book.

43. Teva's Notice Letter states that Teva's ANDA No. 76-898 certifies, pursuant to 21 U.S.C. § 355(j)(2)(B)(i) and (ii)("paragraph IV certification[] with respect to ... the '068 patent"), that the '068 patent is unenforceable and/or would not be infringed by the manufacture, use or sale of its Teva Celecoxib Capsules.

44. Teva has infringed the '068 patent under 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA ANDA No. 76-898, which includes the paragraph IV certification as to the '068 patent and which seeks approval from the FDA to engage in the commercial manufacture, use, or sale of its Teva Celecoxib Capsules prior to the expiration of the '068 patent, which will directly, contributorily and/or induce others to infringe the '068 patent.

45. Upon information and belief, the labeling and/or package insert submitted with ANDA 76-898 states that its Teva Celecoxib Capsules are indicated for the treatment of certain inflammation-associated disorders.

46. Upon information and belief, Teva is committed to selling and intends to commercially sell its Teva Celecoxib Capsules promptly following FDA approval of ANDA No. 76-898.

47. Upon information and belief, Teva has knowingly and willfully infringed the '068 patent.

48. Pfizer will be irreparably harmed if Teva is not enjoined from infringing the '068 patent.

REQUEST FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

1. A judgment providing that the effective date of any FDA approval for Teva to make, use, sell, offer for sale, or import the Teva Celecoxib Capsules described in ANDA No. 76-898 be no earlier than the date on which the '823 or '165 patent terms expire and no earlier than the date on which the '068 patent term expires;

2. An order preliminarily enjoining and a judgment permanently enjoining Teva from making, using, selling, offering to sell, or importing into the United States the Teva Celecoxib Capsules described in ANDA No. 76-898 until after expiration of the '823 or '165 patent terms, and after expiration of the '068 patent term.

3. Attorneys' fees incurred in pursuing this action pursuant to 35 U.S.C. § 285;

4. Costs and expenses incurred in pursuing this action; and

5. Such further and other relief as this Court may determine to be just and proper.

Dated: February 19, 2004

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